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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,701	06/27/2003	Mark V. Vandewalle	5490-000283	9681

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HARNESSE, DICKEY & PIERCE, P.L.C.
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303

EXAMINER

ARAJ, MICHAEL J

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,701

Applicant(s)

VANDEWALLE, MARK V.

Examiner

Michael J. Araj

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 2, 15 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-14, 16-30 and 32-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1002/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group IV shown in Figure 3d in the reply filed on June 28, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is acknowledged that applicant believes claims 1 and 3-41 read on the elected species. The examiner disagrees.

It is noted that comparison of the claims with Figure 3d and the specification shows completely threaded intermediary portion, however, that the species of Figure 3d does not have partially threaded intermediary portion as required in claims 16 and 31.

Claims 16 and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 28, 2005.

Claim Objections

Claims 13, 26 and 27 are objected to for the following informalities:

Claim 13 is objected to for the following reason. There exists an inconsistency between the language of claim 1 and that of the claim 13 dependent thereon, thus making the scope of the claim unclear. In the preamble

Art Unit: 3732

of claim 1, line 1, applicant recites "A bone screw anchor" directing it to the subcombination. However, in claim 13, lines 1 and 2, applicant mentions "the implant as a bone plate" as part of the invention, i.e. "comprising of a bone screw anchor and a bone plate", thus indicating that the combination, the bone screw anchor and the delivery apparatus, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claim 13 will be considered as being drawn to the combination, bone screw anchor and bone plate.

Claims 26 and 27 are objected to for the following reason. There exists an inconsistency between the language of claim 19 and that of the claims 26 and 27 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 19, line 1, applicant recites "A bone screw anchor" directing it to the subcombination. However, in claim 26, lines 1 and 2, applicant mentions "a delivery apparatus" as part of the invention, i.e. "comprising of a bone cement receptacle and a threaded tube connected to the receptacle and operable to cooperate with the threads of the bore", thus indicating that the combination, the bone screw anchor and the delivery apparatus, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the

Art Unit: 3732

language thereof is consistent with this intent. For examination purposes claims 19, 26 and 27 will be considered as being drawn to the combination, bone screw anchor and delivery apparatus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10, 12-15, 17-22, 24, 26, 28-30 and 32-41 are rejected, as understood, under 35 U.S.C. 102(b) as being anticipated by Tronzo (U.S. Patent No. 4,653,489).

Tronzo discloses a bone screw anchor (32) that secures a bone plate (34) to a bone (16) that has and externally threaded intermediary portion; a pointed self-tapping tip, comprising of a cutting flute that extends across a part of the intermediary portion, located at a first end of said intermediary portion; a collared head located at a second end opposite of said tip that has an interface capable with a driving tool; and a threaded interior bore (48) extending through said head and through said intermediary portion, where it is operable with threads of the fastening device (a screw) to secure the implant to the bone (16) and extends completely through said anchor that leads to an open tip (40) for bone cement to

Art Unit: 3732

be directed through (see Fig. 1 below). Tronzo also discloses ports (42, 44) on the sides of the anchor that can communicate with the interior bore that is at least partially filled with bone cement, an intermediary portion that is completely threaded that has a larger diameter than the tip and an interface of said head that has at least one recess operable to mate with said driver. Additionally disclosed is a delivery apparatus (50) comprising of a bone cement receptacle and a threaded tube connected to it that is operable with the threads of the bore. The delivery apparatus (50) further comprises of a stem (46) that extends from the threaded tube, where the stem (46) terminates in a disk operable to plug the bore at the tip to prevent bone cement from passing through said tip.

Tronzo discloses the method steps of securing an implant to a bone which includes implanting a bone screw anchor within the bone using a driving tool operable with the head of the anchor; injecting bone cement into a threaded bore extending through the head to the tip using a cement delivery device that allows the anchor to be secured; and securing the implant to the anchor using a threaded fastening device secure within the bore. Tronzo also discloses that the internally threaded portion is inherently protected during the ejecting step, the delivery device is connected to the internal thread of the anchor to protect the threads from being contaminated with bone cement during the injecting step and the bone cement exits through a tip of the anchor and at least one or more ports located on the side of the anchor (see col. 4, line 49 through col. 5, line 2).

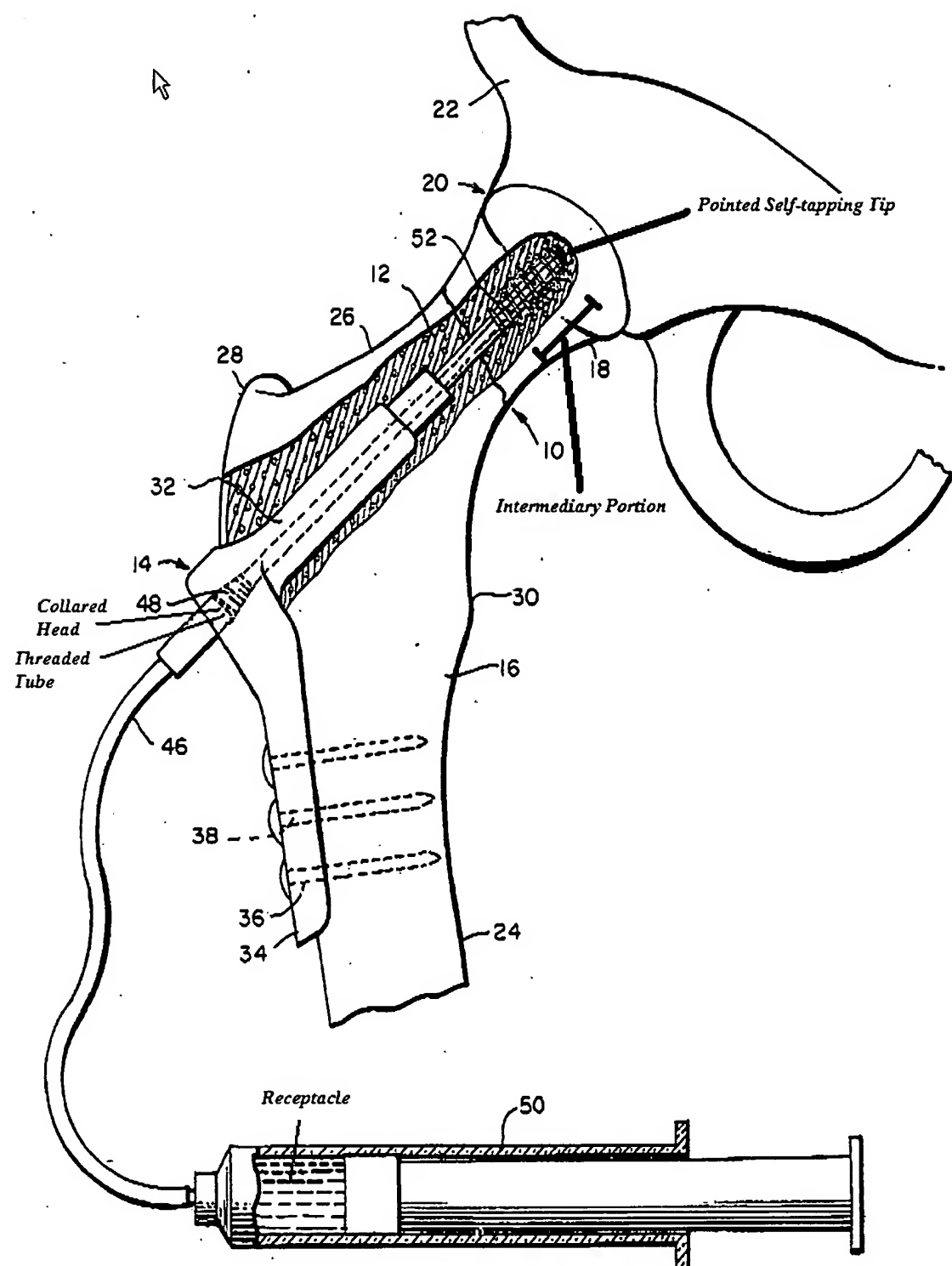


Figure 1

Claims 1, 3-9, 14, 15, 17, 18, 34-36 and 38-41 are rejected, as understood, under 35 U.S.C. 102(b) as being anticipated by Schultheiss et al. (WO 01/12088 A1).

Schultheiss et al. discloses a bone screw anchor (10) that is operable to secure an implant to a bone that has and externally threaded (14) intermediary portion; a pointed self-tapping tip, comprising of a cutting flute that extends across a part of the intermediary portion, located at a first end of said intermediary portion; a collared head, comprising of a cutting flute, located at a second end opposite of said tip that has an interface capable with a driving tool; and a threaded interior (55) bore (50) extending through said head and through said intermediary portion, where it is operable with threads of the fastening device (a screw) to secure the implant to the bone (see Fig. 2 below).

Schultheiss et al. also discloses a port (62) on the sides of the anchor that can communicate with the interior bore (50) that is at least partially filled with bone cement, an intermediary portion that is completely threaded that has a larger diameter than the tip and an interface of said head that has at least one recess (54) operable to mate with said driver.

Schultheiss et al. discloses the method steps of securing an implant to a bone which includes implanting a bone screw anchor within the bone using a driving tool operable with the head of the anchor; injecting bone cement into a threaded bore extending through the head to at least a portion of the intermediary portion using a cement delivery device that allows the anchor to be

Art Unit: 3732

secured; and securing the implant to the anchor using a threaded fastening device secure within the bore. Schultheiss et al. also discloses that the internally threaded portion is inherently protected during the ejecting step, the delivery device is connected to the internal thread of the anchor to protect the threads from being contaminated with bone cement during the injecting step and the bone cement exits at least one port located on the side of the anchor.

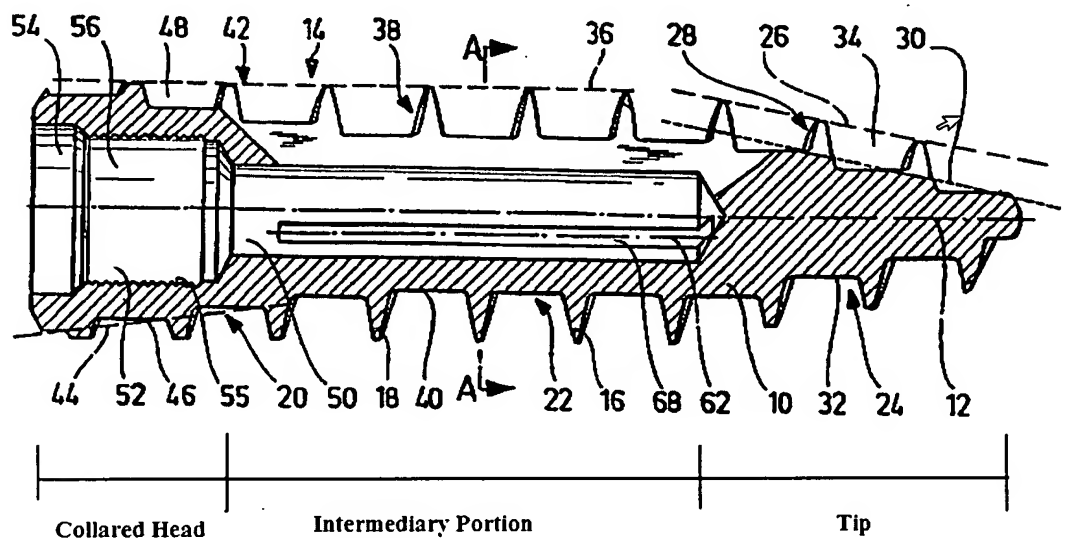


Figure 2

Claims 1, 3, 4, 6, 8, 9, 12, 14, 15 and 17 are rejected, as understood, under 35 U.S.C. 102(b) as being anticipated by Kwan (U.S. Patent No. 5,338,197).

Kwan discloses a bone screw anchor (50) that is operable to secure an implant to a bone that has and externally threaded (53) intermediary portion; a pointed tip, comprising of a cutting flute (64), located at a first end of said

Art Unit: 3732

intermediary portion; a collared head (56), comprising of a cutting flute (70), located at a second end opposite of said tip that has an interface capable with a driving tool; and a threaded interior bore (60) extending through said head and through said intermediary portion, where it is operable with threads of the fastening device (a screw) to secure the implant to the bone (see Fig. 2 below). Kwan also discloses a port (84) on the sides of the anchor that can communicate with the interior bore (60) that is at least partially filled with bone cement, an intermediary portion that is completely threaded that has a larger diameter than the tip and an interface of said head that has at least one recess operable to mate with said driver.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tronzo (U.S. Patent No. 4,653,489).

Tronzo discloses the claimed invention except for the bone screw anchor being made of resorbable material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make this anchor out of resorbable material, since it has been held to be within the general skill of

Art Unit: 3732

a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MJA


EDUARDO C. ROBERT
PRIMARY EXAMINER